

**REMARKS**

This application is amended in a manner to place it condition for allowance.

**Status of the Claims**

Claims 1 and 17 are amended in a manner that is supported by the originally specification with respect to the expandable elements, e.g., on page 9, lines 1-5, 18-25 and 29-32.

Claim 1 is further amended to include the features of claims 2, 3 and 11 and in a manner consistent with the Figure 11.

Claims 4, 12, 13, 15, and 16 are amended to correct the dependency of these claims based on the amendment to claim 1.

Claims 2, 3 and 11 are cancelled.

Claims 1, 4-10, 12-17 remain pending.

**Claim Rejections- 35 USC §112**

Claims 1-17 were rejected under 35 USC §112, first paragraph, for not complying with the written description requirement. This rejection is respectfully traversed.

The position of the Official Action was that the distal movement of the auto-expandable element (24) out of the nose that forces the segments to open out, not the expansion of the element. Claims 1 and 17 have been amended in a manner consistent with this position.

Therefore, the present claims are believed to meet the written description requirement, and withdrawal of the rejection is respectfully requested.

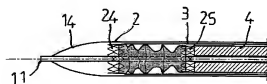
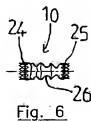
**Claim Rejections- 35 USC §103(a)**

Claims 1-16 are rejected under 35 USC §103(a) as being unpatentable over LINDENBERG et al. US 5,433,723 ("LINDENBERG") in view of MARTINEZ et al. US 5,593,412 ("MARTINEZ"). This rejection is respectfully traversed.

The cited documents fail to teach the claimed invention for at least the following six reasons:

**1. The Implant Structure**

The implant of the present claim 1 includes of two auto-expandable elements at the ends (e.g., 24 and 25 in Figures 6 and 11 shown below) and a hollow intermediate section (26 in Figure 6) that is deformable by twisting:



As mentioned page 6 - line 28 of the originally filed specification, the twist is performed by modifying the relative angle of the two auto-expandable elements.

LINDENBERG, however, relates to an endoprosthesis made from a memory alloy (col. 2, line 13). This endoprosthesis may be formed from a sheet that is spirally wound, expanded metal with rhombic or honeycomb opening, a helically wound wire, cross woven fabrics or knitted fabrics. There is no suggestion of an implant having a hollow intermediate section between two auto expandable elements.

In MARTINEZ, the stent is expandable by an inflatable balloon. The use of an implant of the present invention is not possible with a balloon.

## **2. The Inner Sheath**

As recited in claim 1 and in the specification at several places notably page 9, lines 21-22, the inner sheath (3) is in contact with the first auto-expandable element (24) at its rear end portion and applies on its edge and not on its external surface. Therefore, the inner sheath (3) presses longitudinally on the auto-expandable element (24) for retaining it relatively to the outer envelope, e.g., as shown below:

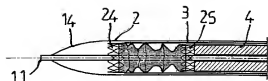


Fig.11

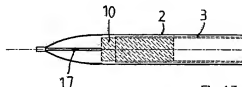


Fig.13

This configuration is of interest in the present invention as when the outer envelope (2) is withdrawn in order to liberate the implant, only the auto-expandable element (24) will be in contact with the internal wall of the nose (14), as illustrated below:

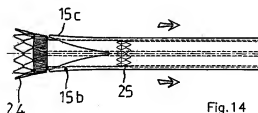


Fig.14

The inner sheath (3), by this longitudinal contact with the auto-expandable element (24), will contribute to rigidify the auto-expandable element (24) to allow the opening of the nose (see page 9 - line 1 to 5 of the specification).

This contact, at the edge of the element (24) is much more efficient for the pushing of the element than what is disclosed in LINDENBERG.

The device of LINDENBERG does not have a nose like the present invention and the endoprosthesis differs from the present

implant. The applicator (3) of LINDENBERG partially overlaps the endoprosthesis on its outer surface. Thereby, the applicator radially constrains the endoprosthesis, and there is no longitudinal contact at the front end piece of the applicator with the endoprosthesis.

MARTINEZ does not disclose an inner sheath or an implant like the present invention. In addition, the nose at the end of the sheath of MARTINEZ device is opened when exposed to warmth as a warm liquid injected in the sheath (col. 3, lines 29-42). There is no indication for opening the nose by the implant or by the balloon. Besides, neither the balloon nor the implant could be sufficiently rigid to open the nose.

Consequently, the combination of the nose of MARTINEZ with the device of LINDENBERG does not lead to the claimed invention.

Instead, the proposed hybrid device comprising the nose of MARTINEZ which is opened by warmth with the LINDENBERG device would not have the nose opened by the endoprosthesis, but by the warmth of the fluid of the body cavity.

Even if one skilled in the art would have modified the nose of MARTINEZ in order to mechanically (rather than by warmth), the endoprosthesis of LINDENBERG would not be sufficiently strong to open the nose as the implant is not longitudinally rigidified by the applicator (3).

### 3. Delivery of the implant

The implant of the claim 1 with its two auto-expandable elements at the two ends and the hollow intermediate section allows for a smooth delivery. When the outer envelope (2) is withdrawn, the auto-expandable element (24) presses against the inner wall of the nose leading to its opening. The auto-expandable element (24) expands gradually functions of the nose opening.

Once the auto-expandable element (24) is expanded and pressed against the inner wall of the body cavity, the hollow intermediate section is delivered. The withdrawal of the outer envelope is easy since the hollow intermediate section which is not expandable does not press against the inner wall of the outer envelope. There is no risk that the implant be displaced.

This, however, is not the case with the LINDENBERG device in which the endoprosthesis which is expandable on all its length would press on the sleeve (2). At the beginning of the delivery, it is only a small portion of the endoprosthesis that presses on the inner wall of the body cavity. The biggest part of the endoprosthesis presses on the sleeve (2) or the applicator (3). Thereby, the force of the contact between the endoprosthesis and the inner wall of the body cavity could be weaker than the force of contact between the endoprosthesis and the device.

Additionally, the endoprosthesis of LINDENBERG would always have a part which would not press on the inner wall of the body cavity between the part already delivered that presses on this inner wall of the body cavity and the part still in the device that presses on the sleeve or on the applicator.

Moreover, the proximal extremity of the endoprosthesis of LINDENBERG has not a sufficient rigidity to open the nose mechanically.

With the device of MARTINEZ, the implant is expanded by the inflation of the balloon once the implant and the balloon are outside the sheath. If the balloon is inflated when implant is still inside the sheath in order to put in contact the implant and the nose, the implant could not be further delivered.

Accordingly, the combination of these two documents also fails to teach a structure similar to the claimed system to deliver the implant as suggested by the claimed structure.

#### **4. The Twist Movement**

The system of the claim 1 comprises an inner sheath (3) which is able to rotate along the longitudinal axis of the device. Once the auto-expandable element is delivered and expanded, the practitioner can rotate the inner sheath relatively to the outer sleeve and the inner wall of the body cavity where the auto-expandable element (24) is fixed.

While the auto-expandable element (24) is fixedly maintained by its contact with the inner wall of the body cavity, the second auto-expandable element (25), still inside the device, is fixedly maintained in contact with the inner wall of the inner sheath. When the inner sheath rotates the second auto-expandable element (25) rotates relatively to the auto-expandable element (24) leading to a twist of the hollow intermediate section and a restriction.

LINDENBERG does not disclose the rotation of the applicator and the elements of the device are not able to rotate as described in column 5. In addition, it relates to an apparatus for widening a stenosis. Therefore, it would be useless and even be opposite to the aim of this document to twist the implant which inevitably leads to a decrease of the diameter of the implant.

Moreover, in order to produce a twist of the endoprosthesis, the two extremities must be firmly maintained by two distinct parts. In LINDENBERG, one extremity of the endoprosthesis is positioned on the body cavity and the other extremity is still positioned in the device by the tongues 4. Nothing indicates that the tongues 4 have a sufficient contact surface with the endoprosthesis to allow a rotation of the latter.

Also, the endoprosthesis described in LINDENBERG is not able to be twisted. This endoprosthesis is expandable along all its length that the force between the endoprosthesis and the



inner wall of body cavity is weaker and does not allow a correct twisting of the endoprosthesis.

The stent of MARTINEZ is expandable by an inflatable balloon going through the stent.

There is no means to allow a twist of the stent.

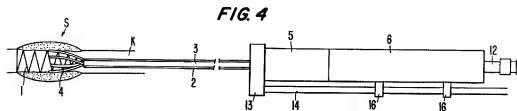
## **5. The Plunger**

The claimed system comprises a plunger (4) mounted so as to slide in the inner sheath and can press against the free end of the second auto-expandable element (25). Like for the inner sheath and the auto-expandable element (24), the contact between the plunger and the second auto-expandable element (25) is longitudinal. The plunger applies on the edge of the second auto-expandable element (25). The second auto-expandable element (25) is maintained by the inner wall of the inner sheath (3). The plunger aims first at preventing the withdrawal of the implant when the sleeve (2) is moved back and then at pushing out the implant in order to finalize its delivery.

The device disclosed by LINDENBERG is different from the invention. When, the sleeve (2) is withdrawn like the outer sheath of the present invention, the applicator (3) and the tongues (34) at its extremity are outside the sleeve (2), as well as the endoprosthesis on all its length.

The opening of the tongues outside the sleeve will partially liberate the endoprosthesis. Actually, when the

endoprosthesis is expanded, as shown in figure 4 below of LINDENBERG, its radially presses against tongues 4 which are trapped between endoprosthesis and the inner wall of the body cavity:



Therefore, if the endoprosthesis is not sufficiently fixed to the inner wall of the body cavity, there is some risks that the endoprosthesis is moved by the withdrawal of the device.

#### **6. Combination with MARTINEZ**

To obtain the present invention of claim 1, one of ordinary skill in the art would only have placed in the sheath of MARTINEZ the endoprosthesis and the applicator of LINDENBERG considered as two combined and not separable elements. So, he would have additionally to remove the sleeve (2) of LINDENBERG to reach the invention. However, there is no hint in MARTINEZ that the sheath might be used to constrain an auto-expandable element. Therefore, one starting from LINDENBERG in order to protect the implant would have placed this whole device in the sheath of the MARTINEZ device without discarding any of its components. With this combination, the invention would not be obtained.

Therefore, the proposed combination cannot render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

**Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/  
Robert A. Madsen, Reg. No. 58,543  
209 Madison Street, Suite 500  
Alexandria, VA 22314  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

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